UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NEW YORK CITY TRANSIT AUTHORITY,	:	
	:	Case No. 1:19-cv-05196
Plaintiff,	:	
	:	
v.	:	**Memorandum in Support of Express Scripts, Inc.'s Motion to Exclude Expert Susan Hayes**
EXPRESS SCRIPTS, INC.	:	
	:	
Defendant.	:	

TABLE OF AUTHORITIES

Cases

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INTRODUCTION[1]

In this lawsuit, NYCTA attempts to hold Express Scripts liable for the cost of compound drug claims that NYCTA paid under its employee prescription drug benefit plan. Express Scripts served as the pharmacy benefit manager ("PBM") for NYCTA's prescription drug plan, pursuant to a written agreement, effective April 1, 2016.[2] NYCTA chose to cover compound drugs, although it was well aware of the high cost of these customized medications.

In addition to encouraging NYCTA to address its compound spend by enrolling in Express Scripts' Compound Management Program, Express Scripts offered NYCTA the opportunity to purchase its Enhanced Fraud Waste and Abuse ("Enhanced FWA") program, which would have provided detailed reports regarding NYCTA's drug spend and searched for patterns or trends that might indicate fraud. NYCTA declined to purchase this service.

NYCTA's compound spend began to increase under its PBM before Express Scripts, and it continued to rise in the first year of Express Scripts' contract. NYCTA believes this rise in compound costs must be due to fraud, and it sued Express Scripts, asserting that Express Scripts should have somehow stopped this supposed fraud. NYCTA retained Susan Hayes as its sole expert witness. *See* Supp. Expert Report of Susan A. Hayes ("Rep."), attached as Ex. 1.[3]

In Opinion One of her Report, Hayes opines that Express Scripts failed to use "reasonable" care because it failed to "identify and/or communicate" to NYCTA "egregious trends" and "red flags" in its compound spend. (Rep. at p. 5, § IV ¶ 1). Hayes' opinion that Express Scripts should have monitored NYCTA's claims data to track for trends contravenes the terms of the parties' Contract, because NYCTA specifically declined to purchase Express Scripts' Enhanced FWA program, which would have provided reports of this exact data. Hayes cannot identify any industry standard or other authority that would require Express Scripts to monitor and track data for trends

[1] Express Scripts is filing contemporaneously herewith a motion for summary judgment. The factual background of is set forth in that motion and its statement of facts ("ESI's SOF"), so Express Scripts does not repeat it herein.

[2] Express Scripts' contract with NYCTA (the "Contract") is attached as Ex. 1 to the Decl. of Elizabeth A. Bozicevic in Support of Express Scripts' Motion for Summary Judgment. Due to the size of this document and the need to file it partially redacted, it is not re-attached here.

[3] All referenced exhibits are attached to the Declaration of Elizabeth A. Bozicevic filed in support of this motion.

when the contractual agreement specifically disclaims this service. Further, this opinion is not tethered to the facts of the case, as Hayes did not review most of the depositions and key parts of the record, and she disregards key facts in what she did review.

Hayes also does not use any reliable, objective "methodology" to reach her opinion. Instead, she simply reviewed charts prepared in 2018 by NYCTA's consultant AON (which compared various aspects of NYCTA's total compound spend under its previous PBM with its total spend under Express Scripts) and jumped to conclusions about what "trends" Express Scripts should have deduced in 2016. Hayes did not review the underlying data, did nothing to validate that AON's summaries were correct, and did not test the claims data to see what trends may have appeared in real time. Hayes' opinion rests entirely upon her subjective beliefs about what, in hindsight, Express Scripts should have known or done two years before AON assembled this data.

In Opinion Two, Hayes opines that Express Scripts did not "properly investigate" Fusion Pharmacy in a "prudent and expert manner."[4] Again, Hayes offers no objective or industry standard that she believes Express Scripts did not meet, and she was not aware of the voluminous record showing extensive investigations and audits that Express Scripts conducted.

Finally, Opinion Three is an impermissible opinion regarding Express Scripts' "motives" to discover any alleged fraud. (Rep. (Ex. 1) at p. 21). Opinion Three is irrelevant, speculative, and prejudicial and should be excluded under Rule 403 as well as Rule 702.

As this Court has recognized, the Court has a "gatekeeping role," and it "is not required to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert . . . . [T]he Court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *In re Gen. Motors LLC Ignition Switch Litig.*, No. 15-CV-1626, 2017 WL 6729295, at *5 (S.D.N.Y. Dec. 28, 2017) (Furman, J.) (citations and quotation omitted).

This Court should preclude Hayes from testifying as an expert, because her opinions are not based upon sufficient facts or data, do not use any reliable principles and methods, and are

[4] Rep. (Ex. 1) at p. 5, § IV ¶ 2.

not reliably applied to the facts, as required by Fed. R. Evid. 702. Hayes' opinions are based upon nothing but her own *ipse dixit* and should be excluded.

LEGAL STANDARD

A witness "qualified as an expert" may offer opinion testimony only if: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702.

"[T]he Supreme Court has made clear that the district court has a 'gatekeeping' function under Rule 702—it is charged with 'the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand.'" *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). The "court must 'make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Id.* at 266 (quoting *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 152 (1999)).

The "court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached," but "conclusions and methodology are not entirely distinct from one another . . . . [N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Id.* (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). "Thus, when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Id.* "[I]t is critical that an expert's analysis be reliable at every step . . . . [This] means that *any* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible.*" *Id.* at 267 (emphasis in original) (citation omitted). "The party

offering the [expert] testimony has the burden of establishing its admissibility by a preponderance of the evidence." *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 411 (S.D.N.Y. 2016).

ARGUMENT

I. Hayes' Opinion One Is Not Admissible Because Hayes Does Not Use Any Reliable Methodology or Standards, and Her Opinion Is Not Tied to the Facts of the Case.

In Opinion One, Hayes opines that in "failing to identify and/or communicate to the NYCTA egregious trends in compound spending readily identifiable in the data it monitors" and "failing to identify certain red flags," Express Scripts "failed to use that degree of care and reasonable diligence that should be applied by a PBM." (Rep. (Ex. 1) at p. 5, § IV ¶ 1). To reach this opinion, Hayes reviewed summary charts prepared in 2018, which compared NYCTA's compound spend under its previous PBM with its spend under Express Scripts, and she opines that there were "spike[s]" that Express Scripts should have identified and communicated to NYCTA. (*Id.* at p. 6-11, ¶¶ 4-8). Hayes' Opinion One does not use any reliable methodology, is purely subjective, and is not tethered to the facts of this case. Her testimony is, therefore, inadmissible.

A. Opinion One is not tied to the facts as it is contrary to the parties' Contract.

First, Hayes' Opinion One is not tied to the facts of this case because it contradicts the terms of the parties' Contract. Opinion One consists of Hayes' belief that Express Scripts should have tracked compound claims by pharmacy and prescriber and communicated such information to NYCTA.[5] Although Hayes acknowledges that Express Scripts informed NYCTA of its compound spend,[6] she believes that Express Scripts "should have [done] a further breakdown" and "reported what the breakdown of those compound claims were."[7]

Hayes' opinion that Express Scripts had a duty to track, monitor, and "break down" the claims data to identify "trends" is inconsistent with the terms of the parties' Contract, which made clear that Express Scripts did not have any such duty. When "expert testimony rests on inadequate factual foundations, problematic assumptions, or a misleadingly partial selection of relevant facts,

[5] Rep. (Ex. 1) at p. 15-16, ¶¶ 23, 29.

[6] Deposition of Susan Hayes (excerpts attached as Ex. 2) at 143:23-144:9.

[7] *Id.* at 137:3-138:9, 179:3-10.

it must be excluded under Rule 702." *Davis v. Carroll*, 937 F. Supp. 2d 390, 418 (S.D.N.Y. 2013). This is particularly true where, as here, an expert "relies on certain assumptions unsupported or contradicted by the record." *Id.* at 419-20 (holding that expert's "failure to reckon with any of the record evidence . . . undermines the reliability of his expert testimony").

As Hayes acknowledged, Express Scripts offered NYCTA an Enhanced FWA program that would have monitored and reported on NYCTA's claims data to track for patterns and trends, but NYCTA declined to purchase this option.[8] The Enhanced FWA "program is designed to help identify outliers and situations of abnormal utilization or prescribing patterns," and clients purchasing the Enhanced FWA program receive detailed reports tracking prescriptions by, *inter alia*, prescription type, pharmacy, prescriber, member utilization, and geographic area.[9]

All of the information that Hayes says Express Scripts should have was provided in the program that NYCTA chose not to enroll in and pay for, as shown in this chart:

Hayes' Opinion	**Enhanced FWA[10]**
Express Scripts failed to inform NYCTA about "major outliers."[11]	"The program is designed to help identify outliers[.]"
Express Scripts failed to identify "pattern[s]."[12]	Program identifies "prescribing patterns," and lists the "patterns identified."
Express Scripts failed to identify multiple prescriptions written by the same prescribers.[13]	Program provides "prescriber advanced analytics," includes "targeting prescribers whose patterns of prescribing indicate fraud."
Express Scripts failed to identify spike in compound drugs.[14]	Program monitors "types of prescriptions, refill patterns and drug utilization."

[8] Am. Compl. ¶ 39. *See also* Hayes Dep. (Ex. 2) at 58:6-14, 62:12-19 ("So a client can buy up that service. So it's the utilization of that specific client"); Contract (ESI's SJ Ex. 1) at § 4.35 ("Fraud Detection and Prevention. Upon [NYCTA]'s request, [Express Scripts] shall administer, for the fees set forth in Exhibit A, a fraud prevention and detention program . . . .").

[9] ESI Dep. Ex. 117 (attached as Ex. 3) at 4-5.

[10] All citations taken from ESI Dep. Ex. 117 (Ex. 3) at 4-5.

[11] Rep. (Ex. 1) at p. 5, § V, Opinion One.

[12] Hayes Dep. (Ex. 2) at 212:3-216:10.

[13] Rep. (Ex. 1) at p. 9-11, ¶¶ 7-8; Hayes Dep. (Ex. 2) at 213:4-216:10.

[14] Rep. (Ex. 1) at p. 7-9, ¶¶ 5-6.

Hayes' Opinion	Enhanced FWA
Express Scripts failed to identify spike in particular pharmacy.[15]	Reports include Retail Pharmacy Audit Summary Report.
Express Scripts failed to identify spike in prescriptions from pharmacy in Utah and should have warned NYCTA that the pharmacy spike was "outside the geographic area."[16]	The "patterns identified" include "geographic prescription drug fraud and abuse concerns."
Express Scripts failed to identify volume of compounds of certain plan members.[17]	Program is designed to "identify beneficiaries who appear to be . . . participating in fraudulent activities"; reporting includes volume and number of prescriptions and drug spend.

Hayes does not and cannot provide any basis for her opinion that Express Scripts should have been tracking the data on a physician, pharmacy, member, or prescription level when Express Scripts offered this service and NYCTA declined to purchase it. Indeed, Hayes acknowledged:

- The Enhanced FWA program was only available to clients who enrolled for an additional fee, and NYCTA declined to pay. (Hayes Dep. (Ex. 2) at 65:9-18).
- Express Scripts had no duty to provide any reports listed in the Enhanced FWA program, because NYCTA "didn't purchase that." (*Id.* at 197:7-198:15).
- The Contract set forth the report package that Express Scripts agreed to provide, and Express Scripts provided all required reports. (*Id.* at 182:25-183:7, 187:25-188:20).

Because Hayes' opinion is wholly inconsistent with the Contract's terms, it fails to meet the basic requirement of Rule 702(d) that an expert "has reliably applied the principles and methods to the facts of the case," and should be stricken for this reason alone. *See Davis*, 937 F. Supp. 2d at 417 n.10 (stating that expert did not "apply those methods reliably to the facts" when expert was "uninformed as about such critical details as what relationship obtained between the participants").

B. Hayes' "experience" working with different PBMs under different contracts is insufficiently tied to the facts of this case to support her opinion.

As stated, Express Scripts did not have any duty to track and "break down" claims data when NYCTA declined to purchase the program that would have done exactly that. In addition to not identifying a contractual duty, Hayes cannot identify an industry standard that would require Express Scripts to "break down" claims by pharmacy, prescriber, and member. Hayes admitted

[15] *Id.* at p. 9-10, ¶ 7.

[16] *Id.*; Hayes Dep. (Ex. 2) at 79:1-22, 213:4-214:13.

[17] Rep. (Ex. 1) at p. 8-9, ¶ 6; Hayes Dep. (Ex. 2) at 189:25-191:14.

that the only basis for her opinion is her "experience" meeting with other PBMs who were operating under different contracts:

> **Q.** [W]hat is the basis for your opinion that Express Scripts should have broken down the spend by pharmacies, prescribers and geographic area[?]
>
> **A.** ··My opinion is based on 25 years of doing this, sitting in hundreds of meetings where PBMs have gone over utilization . . . .[18]

Hayes cannot base her opinion on her "experience" alone when she is not able to identify any standards or industry practice that she obtained from that experience. "All experts testify to some extent based on experience. There must be some verifiable way of demonstrating the validity of each of the items on his list." *Luitpold Pharm., Inc. v. Ed. Geistlich Sohne A.G. Fur Chemische Industrie*, No. 11 Civ. 681, 2015 WL 5459662, at *8 (S.D.N.Y. Sept. 16, 2015) (excluding testimony that was "based on [the expert's] own experience," because it was "merely ipse dixit, not drawn from any verifiable data, even if that data is qualitative"). Further, "[if] the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is applied to the facts. The trial court's gatekeeping function requires more than simply taking the expert's word for it." *Auto. Ins. Co. of Hartford v. Electrolux Home Prod., Inc.*, No. 08-CV-00623, 2010 WL 3655743, at *7 (W.D.N.Y. Sept. 15, 2010) (quoting Rule 702, Advisory Committee's Note (2000 Amendments)).

Here, Hayes cannot show that her experience is tied to the facts of the case because her experience entailed meeting with other PBMs that had different contractual duties. Hayes stated that each PBM contract has different reporting terms, and that the contracts she was aware of have "a clause in there" that they "will bring, you know, utilization trends to the–to the client and work on those trends."[19] When asked if Express Scripts' FWA program is similar to that of other PBMs,

[18] Hayes Dep. (Ex. 2) at 158:9-22. *See also id.* at 179:20-24 ("And my basis for that opinion is 25 years in this business of sitting with clients every quarter and going through what their utilization is . . . .").

[19] *Id.* at 180:16-181:21.

Hayes replied: "I'm not sure. That was not in the scope of what I was asked to do in this case. I have not looked at every PBM's Fraud, Waste & Abuse Program."[20]

Likewise, Hayes could not identify any specific standard governing what information a PBM should communicate to clients. She did not know whether there are any articles or studies on this issue, stating "I have not done research on that" and "I have not seen a book on how PBMs should manage prescription drugs for their clients, no."[21] Rather, she stated, "I don't think that there's a, you know, etched in stone, a manual that requires PBMs to do certain things at these account management meetings."[22]

As such, Hayes' experience with other PBMs with different contracts cannot support her opinion as to what Express Scripts should have reported, because Express Scripts and NYCTA's Contract specifically defined Express Scripts' reporting obligations. An expert "may not opine on broad, undefined obligations that she believes [a party] failed to follow." *Mirena*, 169 F. Supp. 3d at 486-87 (finding expert testimony "impermissible" where expert did "not seem to be basing her opinions . . . on any objective factors . . . and we are left with the vague notion that in her personal opinion Bayer's conduct was inadequate"). Regardless, "[e]xpert opinion on a party's compliance with an industry standard is irrelevant when its obligations are contractually defined." *Luitpold Pharm.*, 2015 WL 5459662, at *8 (concluding opinions "untethered to the contractual standard at issue . . . are irrelevant and would be unhelpful and misleading to the trier of fact").

C. Hayes conceded that her opinion is a subjective, speculative conclusion that cannot be measured against any objective standards.

Opinion One rests upon Hayes' belief that Express Scripts should have reported "spikes" in NYCTA's compound claims. But Hayes' testimony makes clear that her opinion rests on no more than her own subjective conclusion as to when a PBM should report a "spike," stating: "No, ***there's no industry standard*** . . . There's no specific trigger. ***You know it when you see it*** . . ."[23]

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[20] *Id.* at 58:15-59:2.

[21] *Id.* at 88:1-25, 306:24-307:21.

[22] *Id.* at 86:1-15.

[23] *Id.* at. 142:20-143:8 (emphasis added). *See also id.* at 148:5-10 ("I've testified that there is no set-in-stone industry standard other than you kind of know it when you see it.").

Hayes' "you know it when you see it" approach is the antithesis of a reliable methodology because this "methodology is devoid of objective standards that can be tested by others." *Mirena*, 169 F. Supp. 3d at 440, 458; *accord Davis*, 937 F. Supp. 2d at 415 (excluding opinion that "appear[s] to hinge on nothing more than [expert]'s ungrounded speculations about what prices might have seemed reasonable," where expert "did not apply any established methodology . . . [and] d[id] not list and justify the factors used").

Hayes was not aware of any articles, studies, books, or other authority regarding when a PBM should notice "red flags" in data, and she could not identify what level of claims is sufficient to trigger a reporting obligation, other than what "seems excessive" to her.[24] Hayes' inability to identify any ascertainable standard renders her opinion inherently unreliable. *See Mirena*, 169 F. Supp. 3d at 458 (stating that opinion must be excluded "where there is no data, methodology or study underlying the opinion at all"); *Tramontane v. Home Depot U.S.A., Inc.*, No. 15-CV-8525, 2018 WL 4572254, at *7 (S.D.N.Y. Sept. 24, 2018) (excluding opinion where "there is no scientific methodology on which [expert]'s theory can be tested," and where expert opined that level of porosity was "impermissible" but "fails to illuminate . . . what is the acceptable level").

In *E.E.O.C. v. Bloomberg L.P.*, the court excluded expert testimony where it was not supported by any testable methodology, explaining: "Dr. Borgida must provide some explanation regarding his methodology so that it can be evaluated as to its reliability . . . . Upon reviewing Dr. Borgida's report and deposition, the Court cannot discern any reliable method; rather, the opinions in the report are **supported by what appears to be a "*because I said so*" explanation."** No. 07 CIV 8383, 2010 WL 3466370, at *15 (S.D.N.Y. Aug. 31, 2010) (emphasis added) (citations and quotations omitted).

Hayes' standard—"You know it when you see it"—is the exact same sort of "because I said so" methodology that does not pass muster under *Daubert,* as there is no way to test or evaluate its reliability. The Court "cannot simply 'take the expert's words for it' without evidence

[24] *Id.* at 306:24-307:21. *See also id.* at 161:19-163:12 (responding to question about what level of claims required reporting, she stated "I can't tell you that" but $30,000 in claims "seems like, you know, kind of a lot of money").

or a clear explanation." *Scentsational Techs., LLC v. Pepsi*, No. 13-CV-8645, 2018 WL 1889763, at *3 (S.D.N.Y. Apr. 18, 2018), *aff'd*, 773 F. App'x 607 (Fed. Cir. 2019) (citation omitted) (excluding opinion as "ipse dixit, pure speculation, or both" as it was "neither supported by data or analysis nor clearly connected to underlying facts").

D. Hayes did not use any reliable methodology or objective standards other than her own subjective beliefs as to what Express Scripts should have done.

In addition, Hayes' Opinion One did not use a reliable or accepted methodology—indeed, she did not use any cognizable methodology at all. To support her opinion that there were "egregious trends" and "red flags" in NYCTA's compound spend that Express Scripts should have seen, Hayes reviewed unverified and unauthenticated summary charts that AON prepared in 2018, which compared NYCTA's compound spend under Optum (NYCTA's prior PBM) with its spend under Express Scripts, and she concludes that these charts show "spikes" in the data that Express Scripts should have identified and communicated to NYCTA.[25] Based upon this aggregate data compiled by AON in 2018, Hayes jumps to conclusions about what Express Scripts should have deduced in real time, without even reviewing the underlying claims data or doing any testing or analysis of the data to determine what the data might have shown at any time in 2016 or 2017.

Under *Daubert*, the Court must determine "whether a proffered expert opinion has the required indicia of scientific reliability," considering "whether a theory or technique had been and could be tested, whether it had been subjected to peer review, what its error rate was, and whether scientific standards existed to govern the theory or technique's application or operation." *Nimely v. City of New York*, 414 F.3d 381, 396 (2d Cir. 2005). While these factors are not a "definitive checklist," courts are clear that reliability "requires a sufficiently rigorous analytical connection between that methodology and the expert's conclusion. 'Nothing in either *Daubert* or the Federal Rules of evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert.'" *Id.* (quoting *Joiner*, 522 U.S. at 146).

[25] Rep. (Ex. 1) at p. 6-11, ¶¶ 4-8.

"[C]onclusory opinions—often referred to as ipse dixit—fail to provide a methodology that would allow a court to assess reliability." *Scentsational Techs.*, 2018 WL 1889763, at *3.

Hayes' opinion rests only upon her subjective belief as to what she thinks, in hindsight, Express Scripts should have known or done two years earlier. This opinion fails to identify any reliable methodology and should not be admitted, for each of the following reasons.

1. Hayes did not do any testing or analysis, and she did not use the same techniques she uses in her own professional practice.

Looking solely at composite data from 2018 that aggregated claims by member, physician, and pharmacy, Hayes concludes that had Express Scripts "been monitoring compound claims by pharmacy and prescriber," it would have noticed red flags and spikes "much earlier."[26] Hayes did not do any analysis of the underlying claims data to analyze what red flags she believes Express Scripts should have discovered in real time. Rather, her analysis consisted of "you know it when you see it." *See supra*, p. 8-9.

Hayes' company has a system that it uses to analyze its clients' claims data to "score both pharmacies and claims" for "potential fraud, waste and abuse." The patented system "uses a series of proprietary algorithms to score both pharmacies and claims . . . . Such algorithms include the density of the association of prescribers, patients and pharmacies."[27] Despite touting that system in her Report, Hayes did not use it in her analysis. Hayes received "detailed claims data" from NYCTA, but she "did not run them through our system," stating: "No, **there's no reason why I didn't**, other than–other than our system is extremely complicated and there's a lot of rules around the data that would preclude me from doing this on a one-off basis."[28]

"Ultimately, the *Daubert* reliability inquiry is designed 'to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Gen. Motors*, 2017 WL 6729295, at *5 (quoting *Kumho Tire*, 526 U.S. at 152);

[26] Rep. (Ex. 1) at p. 12-16, ¶¶ 11, 23, 29).

[27] *Id.* at p. 1-2, ¶¶ 4-6. *See also* Hayes Dep. (Ex. 2) at 47:4-49:3.

[28] Hayes Dep. (Ex. 2) at 49:20-51:2 (emphasis added).

Amorgianos, 303 F.3d at 265-66 (same). This standard cannot be met where, as here, **Hayes did not even use her own methodology** to analyze the data underlying her opinion. *See Amorgianos*, 303 F.3d at 268-69 (affirming exclusion of expert's testimony as "unreliable" when expert "failed to apply his own methodology reliably"); *Davis*, 937 F. Supp. 2d at 416 (finding expert testimony unreliable where expert "did not actually apply any of the well-established methods . . . that he helped to develop").

2. Hayes failed to validate the data she used to form her opinion.

Hayes' reliance upon AON's summary charts is further devoid of any reliability because Hayes did not validate (or even review) the underlying claims data or verify that AON's data summaries were accurate. This alone warrants exclusion of her opinion.

Federal courts routinely find that "[a] failure to validate data by itself can constitute grounds for excluding an expert report." *Forte v. Liquidnet Holdings, Inc.*, 675 Fed. App'x 21, 23-24 (2nd Cir. 2017) (affirming exclusion of expert testimony where expert did not verify any of the data used but simply input the numbers given). In *Dreyer v. Ryder Auto. Carrier Grp., Inc.*, the court excluded an expert when he utilized data prepared by a consultant and "made no effort to independently verify the accuracy." 367 F. Supp. 2d 413, 446 (W.D.N.Y. 2005). The court held:

> Where an expert fails to verify the accuracy of data upon which the expert creates a statistical analysis or renders an opinion, the resultant analysis and opinion are inherently unscientific requiring exclusion of such evidence under *Daubert* . . . .
>
> . . . As [opinion] . . . is founded upon unverified and therefore potentially incomplete and inaccurate data, it is inadmissible for lack of compliance with Rule 702's requirement that data upon which a proposed expert's testimony is based be 'sufficient.'

Id. (citations omitted). *See also In re Med Diversified, Inc.*, 334 B.R. 89, 100 (E.D.N.Y. 2005) (excluding expert testimony where expert testified that "he did not independently analyze the data from the databases from which he derived his figures").

Hayes did not talk to anyone at AON or review any AON testimony about the charts.[29] She also did not review any of the Optum or Express Scripts data that AON used to compile the charts,

[29] Hayes Dep. (Ex. 2) at 105:7-12.

and she testified that she did not ask for it because "it wasn't relevant to me."[30] Hayes did receive Express Scripts' claim data, and she acknowledged that she could have looked at it to verify the accuracy of AON's charts, but she did not do so.[31] Hayes simply "assumed" that the summaries she was provided were correct:

> **Q.** You didn't–you didn't use any of that claim data to verify the accuracy of any of the charts that are contained in your Report true?
> **A.** True. Not these charts, correct.
> **Q.** And–and you didn't do any testing or validation of the charts that are contained in your Report correct?
> **A.** No. I assumed that they were produced under subpoena, they were correct.
> ***
> **Q.** You - you did nothing more than copy them from the–from Aon's presentation, correct?
> **A.** Correct.[32]

Hayes' blind reliance on AON's summary charts without making any attempt to validate the underlying data herself alone requires exclusion of this testimony. *See Dreyer*, 367 F. Supp. 2d at 446 (excluding expert report where expert "admitted that while he believed the data were complete, he had no first-hand knowledge of such fact and had accepted the data that had been garnered by [] Defendants' consultant . . . without verifying its accuracy because he '*relied on* [the consultant] for this information'" (emphasis in original) (citations omitted)).

3. Hayes did not control for any variables or consider other factors.

Hayes' methodology is also fundamentally flawed because she did not control for any variables. Hayes looked at total claims costs and summarily concluded that Express Scripts should have noticed a "spike" in compound claims between the period when Optum was NYCTA's PBM and when Express Scripts was PBM, but she did not consider any variables that might have caused this cost increase—including changes in time frame, plan terms, membership, or other factors.

"To be reliable, a data analysis must account for major variables[.]" *Lamarr-Arruz v. CVS Pharmacy, Inc.*, No. 15-CV-04261, 2017 WL 4277188, at *10-*11 (S.D.N.Y. Sept. 26, 2017)

[30] *Id.* at 107:16-108:13, 131:3-7.

[31] *Id.* at 123:18-125:14, 132:8-133:11.

[32] *Id.* at 111:23-112:18. *See also id.* at 108:14-17.

(collecting cases) (holding that expert's "failure to investigate the impact of these major variables, let alone control for them, renders his proposed testimony unreliable"). *See also Wills v. Amerada Hess Corp.*, 379 F.3d 32, 50 (2d Cir. 2004) (Sotomayor, J.) (affirming exclusion of testimony where expert's "fail[ure] to account for these variables . . . strongly indicated that [expert]'s conclusions were not grounded in reliable scientific methods, as required by *Daubert*").

For example, Hayes compared NYCTA's aggregate monthly spend under Optum to its aggregate monthly spend under Express Scripts, but she did not compare the number of plan members under Optum versus Express Scripts, and she did not compare the benefit plans for differences in coverage.[33] Similarly, Hayes compared the top beneficiaries under Optum and Express Scripts, but she did not look to see if any of the top members under Express Scripts were even members under Optum, and vice versa.[34] Further, while she shows that these members' *total* number of prescriptions and costs were higher under Express Scripts, she did not take into account that the Express Scripts data covered eight months more than the Optum data.[35]

"It is plain that one cannot determine whether something caused an observed effect without controlling for other equally plausible causes of that effect." *R.F.M.A.S., Inc. v. So*, 748 F. Supp. 2d 244, 273 (S.D.N.Y. 2010). Hayes' utter failure to account for or even acknowledge how other factors could impact her analysis further renders her methodology unreliable.

4. Hayes' opinion is an apples-to-oranges comparison.

Hayes cites an article stating that 1-3% of prescriptions in the United States are for compound drugs, and asserts that "[c]laim volumes in excess of this national benchmark should have been a flag to ESI that there was a problem that should have been investigated."[36] Hayes' methodology using this statistic as a "benchmark" is faulty in at least two respects.

[33] Rep. (Ex. 1) at p. 6-7, ¶ 4; Hayes Dep. (Ex. 2) at 113:24-114:14.

[34] Rep. (Ex. 1) at p. 8-9, ¶ 6; Hayes Dep. (Ex. 2) at 127:6-11, 130:13-131:12.

[35] Hayes Dep. (Ex. 2) at 128:13-23.

[36] (Rep. (Ex. 1) at p. 11-12, ¶ 10).

First, Hayes does not know whether NYCTA's compound spend exceeded her 1-3% standard because she only looked at its compound spend and did not know its *total* prescription spend.[37] Any comparison to a supposed "benchmark" is meaningless when Hayes had no idea how NYCTA's compound spend compared to that benchmark.

Second, NYCTA's compound spend cannot be compared to this "benchmark" because NYCTA's plan had no limits on compound drugs, whereas most health plans have programs limiting coverage.[38] Since NYCTA's unrestricted compound coverage was an outlier, comparing NYCTA's unrestricted compound spend to data of plans with compound limitations is an apples-to-oranges comparison. An expert's "failure to make any independent showing of representativeness [of data] renders his testimony unreliable and inadmissible." *Apple v. Atlantic Yards Dev. Co.*, No. 11-CV-5550, 2015 WL 11182422, at *6 (S.D.N.Y. Mar. 31, 2015) (excluding opinion because of expert's "assumption that national survey data is necessarily representative of the New York union members" at issue). *See Roniger v. McCall*, No. 97 Civ. 8009, 2000 WL 1191078, at *3 (S.D.N.Y. Aug. 22, 2000) (holding that the "statistical data [expert] cites is too general to render his opinion reliable," as it was not limited to similar situations).

5. Hayes' opinion is based upon nothing but the results.

At bottom, Hayes' opinion is that because NYCTA's compound spend was high, Express Scripts must have done something wrong. Hayes looked at the February 2018 AON data and summarily concluded that Express Scripts must have been at fault:

> **Q.** And so is the basis of your opinion that Express Scripts didn't do what you believe the industry standard required it do because the compound spend increased?
>
> **A.**· Yes.· That is my opinion.· Those are the facts in the matter, that compounds continued to -- continued to run, you know, in the millions of dollars a month for a period through '16 and into '17.[39]

[37] Hayes Dep. (Ex. 2) at 151:4-153:19. In fact, Hayes testified that what percent of NYCTA's total prescription drug spend was compound drugs was not "relevant to my opinion." *Id.* at 152:15-25.

[38] Hayes Dep. (Ex. 2) at 201:21-202:1. *See also* Deposition of Jim Masella (excerpts attached as Ex. 4) at 197:19-198:18 (testifying that NYCTA was an "outlier" and one of the few plans that had not have compound controls).

[39] Hayes Dep. (Ex. 2) at 146:10-18. *See also id.* at 147:7-148:24, 159:10-12 ("I'm looking at the results. The results are spend continued and it was not managed well.").

In other words, Hayes believes that had Express Scripts done **something** different, it might have discovered the increased spend sooner, but she completely glosses over what that "something" is, nor can she identify any industry or contractual standard that would have **required** Express Scripts to do that other act. Hayes' opinion simply works backwards from a conclusion—NYCTA's compound spend was high—and concludes that Express Scripts caused the increase.

It is precisely this type of reverse-engineering that undermines the reliable scientific methodology required by *Daubert* and Rule 702. *See Gen. Motors*, 2017 WL 6729295, at *8 (excluding testimony that "did little more than work backwards from" the incident). "Such testimony does not reveal the scientific method at work; instead, it reveals Plaintiffs' experts to be reverse-engineering a theory to fit the desired outcome." *Id.* (citing *Mirena*, 169 F. Supp. 3d at 430). *See also Mirena*, 169 F. Supp. 3d at 430 (finding that when expert "was given a conclusion by lawyers and worked backwards to hypothesize a mechanism by which it might occur[,]" this "reverse-engineering a theory to fit the desired outcome . . . alone would warrant exclusion").

Hayes' "leap is the essence of unverifiable subjectivity, amounting to the sort of *ipse dixit* connection between methodology and conclusion that the district court has the duty to exclude under Rule 702." *Nimely*, 414 F.3d at 399.

E. Opinion One is not a "fit" because Hayes did not consider the factual record.

Hayes' opinions are further inadmissible because they are not "based upon sufficient facts or data" and she has not "applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702(b), (d). Hayes' wholesale failure to consider the factual record goes beyond the weight of her testimony but, rather, renders her entire testimony unreliable and inadmissible.

When an expert fails to review relevant documents, her opinion is "based on insufficient facts and data" and is "unreliable." *Faulkner v. Arista Records LLC*, 46 F. Supp. 3d 365, 381 (S.D.N.Y. 2014) (holding that expert's "refusal to ask for such evidence, his failure initially to review many categories of records, and his disregard of such relevant records after his belated review indicate that his methodology was aimed at achieving one result"). "[A]n expert's analysis fails to meet the *Daubert* standard where it is based on incorrect factual assumptions that render

all of [expert's] subsequent conclusions purely speculative." *Gen. Motors*, 2017 WL 6729295, *9 (citation omitted). *See also In re Gen. Motors Ignition Switch Litig*, 14-MD-2543, 2016 WL 4077117, at *6 n.7 (S.D.N.Y. Aug. 1, 2016 (excluding testimony when expert "lacks any factual basis to proffer it in relation to Plaintiff's case" as he had "no knowledge" of the relevant facts).

1. Hayes' opinion that Express Scripts should have notified NYCTA of its compound spend ignores the factual record.

In Opinion One, Hayes opines that Express Scripts should have "brought it to the attention of New York City Transit that there was a spike in compound utilization," and she testified that she believed Express Scripts should have had "quarterly meetings" with NYCTA to discuss its "utilization" and "come up with remedies or solution."[40] In fact, Express Scripts and NYCTA did have quarterly meetings where they discussed NYCTA's compound spend, but Hayes did not "know what was discussed at these meetings between Express Scripts and New York City Transit," because she did not review the depositions of any NYCTA or Express Scripts employees involved in those meetings, saying they were "not relevant to my opinion."[41] This avoidance of key facts renders her opinion inadmissible. *See R.F.M.A.S.*, 748 F. Supp. 2d at 273 (finding that when experts "did not even bother to read the deposition[s]," their conclusions were "simply a reflection of" their "lack of investigation" and the fact that they did not review any contrary evidence).

Had Hayes reviewed the record, she would have known that Express Scripts met with NYCTA quarterly, providing NYCTA in these meetings with reports showing its utilization and spend by drugs and drug categories (including compounds) and offering various solutions. For example, Hayes ignores—or is unaware of—the following facts:

- At the first quarterly meeting held, Express Scripts provided NYCTA with a report covering the first five months of the relationship (April-September 2016), which showed NYCTA's total compound spend and indicated that compounds were NYCTA's #1 drug cost.[42]

[40] Hayes Dep. (Ex. 2) at 80:7-81:7, 85:1-87:25, 90:4-91:2.

[41] *Id.* at 23:16-22, 144:16-145:6, 146:3-9, 158:23-159:12. *See also id.* at 66:6-23 ("I formed my opinion without–I felt that I formed my opinion looking at the documents that I looked at and did not need to consider [NYCTA's Jim Masella's] opinion–or his testimony. I'm sorry.").

[42] ESI Dep. Ex. 11 (attached as Ex. 5) at 9-10; Masella Dep (Ex. 4) at 117:6-123:5.

- In that same quarterly report, Express Scripts informed NYCTA that "the ESI Compound Management Solution can drive a ~95% decrease in compound plan cost." Express Scripts offered several "Solutions," including the Compound Management Program (at no charge), or the Fraud, Waste and Abuse Program for a fee, which would "identify and review outliers" and "flag suspicions for investigative review."[43]
- On March 1, 2017, Express Scripts presented a Collaborative Planning Guide, which informed NYCTA that its compound spend from April-December 2016 was $21.7 million and remained its number one drug cost, with a breakdown of number of claims per month.[44]
- On December 7, 2018, Masella emailed others at NYCTA, saying: "Here's the JULY 2016 PowerPoint presentation from ESI on compounds on how we should control our spend. This is months before spend spiked for us. We knew compounds were a problem so I worked with OPTUM and then ESI to determine what we could do to manage our spend."[45]

Hayes' opinion that Express Scripts should have brought the "spikes" in compound spend to NYCTA's attention is further belied by NYCTA's own pleadings, in which NYCTA states that it was well-aware of it, alleging: "The NYCTA in-house plan administration staff first noticed these spikes early and in real time." (Am. Compl. ¶¶ 5, 48). Jim Masella, who was responsible for NYCTA's benefit program, testified that his staff was able to, and did, run reports to identify pharmacies and prescribers with a "spike in compounds."[46]

Hayes' "failure to reckon with any of the record evidence . . . undermines the reliability of [her] expert testimony." *Davis*, 937 F. Supp. 2d at 418-19 (holding that expert could not testify about lack of "red flags," because his opinion was based upon "factual assumptions" that "lack *any* basis in the record" and contradict the actual evidence) (emphasis in original). *See also Bloomberg*, 2010 WL 3466370, at *15, *17 (excluding testimony where expert "only analyzed material provided and selected" by the plaintiff because "[t]o ignore contradictory testimony in order to arrive at a desired conclusion highlights the unreliability of [an expert's] methodology").

[43] ESI Dep. Ex. 11 (Ex. 5) at 10, 21, 27-29; Masella Dep. (Ex. 4) at 129:3-130:7 ("Q. And Express Scripts told you about this [Enhanced FWA] program in at least here, September 2016, correct? A. Right.").

[44] Express_Scripts_1095_00003144-Express_Scripts_1095_00003178 (attached as Ex. 6) at 8, 9, 27.

[45] NYCTA000019844-NYCTA000019851 (attached as Ex. 7).

[46] Masella Dep. (Ex. 4) at 160:14-161:23. *See also id.* at 105:14-106:15 (testifying that his staff had the ability to "run reports and identify these pharmacies for me"), 156:25-157:12 ("Mary [with NYCTA] kept running the reports for me and kept identifying these pharmacies . . . . But I wanted [Express Scripts] to produce a report that Mary produced.").

Hayes testified that under the "industry standard," a PBM should have quarterly meetings to discuss "ways to better manage that utilization," and that when she attended meetings with other PBMs, "solutions" discussed included: "Either blocking compounds at some level, some dollar level, or prior-authorizing those, or eliminating the pharmacy from the network."[47] In fact, Express Scripts offered all of these solutions. With respect to blocking compounds or requiring pre-authorization, Express Scripts repeatedly recommended that NYCTA do just that, but NYCTA refused to do so.[48] Express Scripts recommended to NYCTA that it implement this Compound Management Program before the Contract was signed and throughout the relationship.[49]

The parties agree that the Compound Management Program would have lowered NYCTA's compound spend. Hayes acknowledges this as well, noting that the Department of Defense's prescription drug program (Tricare) experienced a rise in compound claims and fraudulent activity, but those costs "stabilized once Tricare implemented [Express Scripts'] Compound Management Solution."[50] After NYCTA discovered that an NYCTA employee had been running a fraudulent scheme, Masella told his colleagues at NYCTA: "This could have been prevented by implementing the compound medication program we discussed."[51]

In sum, Hayes' opinion ignores the facts in the record, which establish that NYCTA was well aware of its compound "spike," and rejected any solutions offered by NYCTA.

2. Hayes' opinion that Express Scripts should have terminated Fusion as a "solution" has no factual basis.

Hayes testified that the only other "solution" that Express Scripts should have offered was to eliminate Fusion Pharmacy (the pharmacy that filled the largest total volume of compound

[47] Hayes Dep. (Ex. 2) at 87:10-25, 91:3-12.

[48] *Id.* at 91:13-92:10.

[49] *See* Masella Dep. (Ex. 4) at 72:18-74:5 (acknowledging that Express Scripts' standard process is to enroll clients in the Compound Management Program and that NYCTA opted out), 74:8-76:5 (agreeing that NYCTA declined to implement compound controls upon Express Scripts' offer in March 2016), 79:16-80:14 ("Q. Now, prior to April 1st of 2015, Express Scripts recommended to the Transit Authority that it implement the Compound Management Solution, correct? A. Yes . . . ."); Ex. 5 at 10; Ex. 6 at 9.

[50] Rep. (Ex. 1) at p. 16, ¶ 28.

[51] ESI Dep. Ex. 31 (attached as Ex. 8). *See also* Masella Dep. (Ex. 4) at 215:19-23 (testifying to same).

claims) from its network.[52] Hayes' conclusory opinion that Express Scripts should have just "eliminated Fusion from the network" to solve the problem is divorced from any factual basis.

First, Hayes' opinion that Express Scripts should have terminated Fusion by June 2016 has no basis in the data she reviewed because she only reviewed AON's data summaries that contained the *aggregate* (not the monthly) claims as of February 2018. Hayes admitted she did not know how much Fusion dispensed per month in April or May 2016, or how much "Fusion contributed to that spike," because she did not review the claims data.[53] Hayes' opinion as to what Express Scripts should have known in June 2016 and done in response is pure speculation.

Second, Hayes failed to consider the terms of Express Scripts' contract with Fusion, which provides the grounds for which Express Scripts could have terminated Fusion from its network.[54] Express Scripts investigated Fusion several times and found no evidence of fraud. *See infra,* § IV. Hayes admitted that she has no basis for any opinion that Fusion was actually involved in fraud and has seen no evidence that Fusion submitted any claims to Express Scripts that did not have a valid prescription or that a member did not receive.[55]

Finally, the ultimate fact is that *Fusion was not the problem*. The problem was that NYCTA covered compound drugs, without limitations, restrictions, or prior authorization requirements.[56] NYCTA knew that terminating Fusion from the network would not fully solve its problem, as members could just fill prescriptions at another pharmacy. As NYCTA's benefits coordinator said when he directed Express Scripts to block Fusion: "Even though I shut down Fusion . . . I'm still concerned that the root of the problem hasn't been dealt with. It's like a balloon,

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[52] Hayes Dep. (Ex. 2) at 94:1-96:9 ("Q. And what should Express Scripts have done? A. They should have eliminated Fusion from the network . . . Q. Any other strategies that Express Scripts should have come up with or recommended? A. No. I think that would have taken care of the problem here. Q. When should Express Scripts have brought Fusion to New York City Transit's attention? A. Very early on in the relationship; April, May, June of 2016.").

[53] *Id.* at 135:24-137:2, 139:11-18, 160:19-161:18.

[54] *Id.* at 222:20-223:5, 247:21-24.

[55] *Id.* at 253:17-256:22.

[56] At the end of 2018, after NYCTA had blocked a number of pharmacies and prescribers from its network, its compound spend was still approximately $700,000/month; after it implemented Express Scripts' Compound Management Program, the compound spend dropped to $39,000/month. *See* Masella Dep. (Ex. 4) at 210:14-23.

squeeze one end that the other end pops out."[57] Masella explained: "[W]hat I meant was that if you shut down the pharmacy the physician will just send the prescription to another pharmacy."[58]

Hayes cannot explain how terminating Fusion would have changed anything, as the prescriptions could have just been filled elsewhere. Indeed, after NYCTA finally adopted the Compound Management Program, NYCTA instructed Express Scripts to put all of the blocked pharmacies—including Fusion—back into its network.[59] As such, Hayes' proposed "solution" is completely untethered to the facts or to the reality of the situation.

II. Hayes' Opinion Two, Regarding Express Scripts' Investigation of Fusion Pharmacy, Is Not Based Upon Any Reliable Methodology or Standard and Not Tied to the Facts.

In Opinion Two, Hayes opines that Express Scripts did not "properly investigate" Fusion Pharmacy.[60] Like Opinion One, this Opinion is not based on any identifiable standards, focuses on what industry standards *should* be as opposed to what they are, and ignores the factual record.

For example, Hayes opines that Express Scripts was "negligent" because it "employs non-investigative personnel to perform the work of claims investigation."[61] However, in an article published by Hayes, she stated that most PBMs do not do the type of investigation, using licensed investigators, that she opines Express Scripts should have done:

> Some PBM fraud programs may send auditors to a small number of pharmacies to determine if the pharmacy has the proper paperwork . . .
>
> **These procedures, however, are recordkeeping investigations rather than true fraud investigations. Many of the auditors may have little or no law enforcement/private investigation experience** . . . and may not properly prepare a case for prosecution. **They also may lack the legal authority to investigate a pharmacy,** since many states require any person who investigates claims . . . to be a licensed private investigator.[62]

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[57] NYCTA000004848-NYCTA000004849 (attached as Ex. 9).

[58] Masella Dep. (Ex. 4) at 159:9-161:23.

[59] *Id.* at 211:18-214:14.

[60] Rep. (Ex. 1) at p. 5, § IV, ¶ 2; p. 16, § V, Opinion Two.

[61] *Id.* at p. 18, ¶¶ 10-11 (opining that Express Scripts employee performing investigation of Fusion was not a licensed "investigator" and "should have referred to himself as an auditor").

[62] Susan Hayes, "Finding and Preventing Prescription Drug Fraud," Benefits Magazine, June 2017, at 21 (attached as Ex. 10) (emphasis added).

Express Scripts' practices are consistent with what Hayes believes other PBMs are doing, but she thinks *all PBMS* should do more. Hayes testified that she had "no idea" if other PBMs use "licensed investigators" in their FWA investigations.[63] She also testified that it does not matter what other PBMs do, arguing, "[D]idn't your mother say, you know, growing up that, 'If'–'If all the rest of the kids do it, doesn't mean you can do it.'"[64] But this is precisely what an industry standard is—it is what others in the industry are doing. Hayes may not like the industry standard, but it is not her role to testify as to what she thinks the standard should be. Expert testimony is not "reliable evidence of existing industry practices" when the expert is "'recommending a standard of care,' not describing an existing industry practice in the real world." *In re M/V MSC FLAMINIA*, No. 12-CV-8892, 2017 WL 3208598, at *33-*34 (S.D.N.Y. July 28, 2017).

Similarly, Hayes is critical of Express Scripts for taking the word of pharmacies, physicians, and members during investigations.[65] Although Hayes agreed that Express Scripts followed standard investigation practices by requesting information from pharmacies, physicians, and members as part of the investigation into the pharmacy,[66] and although she agrees that Express Scripts asked Fusion to provide copies of delivery receipts and asked members if they received the medications, she believes Express Scripts should have gone one step further and double-checked that the medications were delivered by reviewing UPS or FedEx tracking numbers.[67] Hayes' basis for this opinion—that delivery receipts and member statements must be reviewed against UPS tracking—is that it is her practice, and she has heard that others do it, but she acknowledges that "there's no bible on industry standard here" and that there are no articles or studies supporting her opinion that review of UPS tracking data is a necessary investigatory practice.[68] Hayes identified no other method for verifying the statements of pharmacies, prescribers, or members.

[63] Hayes Dep. (Ex. 2) at 269:16-270:19.

[64] *Id.* at 270:20-271:8.

[65] Rep. (Ex. 1) at p. 18-19, ¶¶ 11-14; Hayes Dep. (Ex. 2) at 232:11-233:15.

[66] Hayes Dep. (Ex. 2) at 231:4-22, 233:16-234:12, 236:20-237:23.

[67] *Id.* at 233:16-235:17.

[68] *Id.* at 238:8-239:16.

Hayes' opinion ignores the factual record, as she did not consider a number of documents that she admits would have been relevant to her opinion. For example, Hayes believes that a proper investigation of Fusion would have included an on-site audit, and that it would have been relevant to her opinion if an on-site audit had occurred.[69] She also believes that Express Scripts should have looked at more prescription drug claims than the "dozen or so" that were reviewed in the documents she saw.[70] However, when shown two spreadsheets summarizing 54 Fusion claims reviewed by Express Scripts during an *on-site* audit and another 42 claims otherwise audited by Express Scripts, Hayes acknowledged that she had never seen the spreadsheets or the information in them.[71] Hayes also testified that Express Scripts should have received purchase information from Fusion's suppliers, and that it would have been relevant to her opinion if Express Scripts received such information.[72] Express Scripts produced almost 100 documents that it received from Fusion's suppliers during the investigation Hayes reviewed. Hayes just did not look at them.

At bottom, Hayes' opinion is that Express Scripts should have done a "more thorough investigation."[73] But this opinion is based solely upon her wished-for standards and her incomplete knowledge of the factual record.

III. Opinions One and Two Contain Inappropriate Legal Conclusions.

In addition, Hayes' opinions must be excluded because they contain impermissible legal conclusions. Hayes opines that Express Scripts did not "process, monitor, investigate, and/or review claims in a prudent and expert manner," and "failed to use that degree of care and reasonable diligence that should be applied by a PBM."[74] She also opines that Express Scripts failed to investigate "in a prudent and expert manner" and that its investigation was "inadequate."[75]

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[69] *Id.* at 251:14-20, 252:1-6.

[70] *Id.* at 258:2-259:25.

[71] *Id.* at 279:5-280:9, 281:7-282:14 (reviewing ESI Dep. Exs. 125 and 126). These exhibits were previously marked as NYCTA Dep. Exs. 113 and 114, and they were identified as the desk and field (on-site) audit results for the pharmacies blocked by NYCTA. (Deposition of Blake Stockwell, excerpts attached as Ex. 11, at 214:5-18, 229:3-16).

[72] Hayes Dep. (Ex. 2) at 240:7-24.

[73] *Id.* at 256:13-16.

[74] Rep. (Ex. 1) at p. 5, § IV, ¶ 1; p. 5, § V, Opinion One.

[75] *Id.* at p. 5, § IV, ¶ 2; p. 16, ¶ 3.

An expert cannot testify whether a party's action "was unreasonable," because an expert may "not express an opinion directly on the legal conclusion." *McBeth v. Porges*, No. 15-CV-2742 2018 WL 5997918, at *6 (S.D.N.Y. Nov. 15, 2018) (Furman, J.) (citation omitted); *accord Roniger*, 2000 WL 1191078, at *5 (stating that expert could not testify as to whether party's actions "were 'reasonable' because this is an ultimate question in this case which is for the jury to decide based on all the evidence and this Court's instructions"). Similarly, an expert may not "present opinions in the form of legal conclusions regarding the reasonableness or prudence of a defendant's actions, or the scope of the defendant's knowledge." *M/V MSC FLAMINIA*, 2017 WL 3208598, at *18. Hayes' opinions regarding whether Express Scripts acted with "reasonable diligence," in a "prudent and expert manner" and complied with the statute are inadmissible legal conclusions and must be excluded.

IV. Opinion Three Should Be Excluded because It Is an Improper Opinion as to Express Scripts' Motives, and It Is Irrelevant and Unduly Prejudicial.

In Opinion Three, Hayes opines that Express Scripts' "spread pricing model"[76] gave it financial incentives to process excessive compound prescriptions and removed any "incentives to control for FWA."[77] Hayes believes that because Express Scripts gets paid for each claim, it has an incentive to process as many claims as possible, without regard to whether the claim is valid.

Opinion Three should be excluded because it is an improper opinion as to Express Scripts' motives. Hayes freely acknowledges that her opinion goes to motive:

> **Q.** And so if I hear – if I understand your opinion, is it that Express Scripts has no motive or incentive to control fraud, waste and abuse due to spread pricing?
>
> **A.** That is my opinion, yes.[78]

[76] Spread pricing is the "traditional pricing" model for PBMs, in which PBMs are paid for its services by charging its plan sponsors more than Express Scripts reimburses pharmacies and keeping the difference, the "spread." (Rep. (Ex. 1) at p. 21, ¶¶ 1-2; Hayes Dep. (Ex. 2) at 283:5-8). Spread pricing is common in the PBM industry, and it was the method of pricing selected by NYCTA when it drafted the Contract. (Hayes Rep. (Ex. 1) at p. 21, ¶¶ 1-2; Contract (Ex. 1 to ESI's SOF) at Exhibit I (describing the pricing structure as spread pricing)).

[77] Rep. (Ex. 1) at p. 21, ¶ 2.

[78] Hayes Dep. (Ex. 2) at 287:2-6. *See also id.* at 292:3-13 ("[S]pread pricing would give you a motive for not investigating and turning off the spigot of compound prescriptions.").

It is well established that "[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony." *Saxon Glass Techs., Inc. v. Apple Inc.*, 393 F. Supp. 3d 270, 293-94 (W.D.N.Y. 2019), *aff'd*, 824 F. App'x 75 (2d Cir. 2020) (citation omitted); *R.F.M.A.S.*, 748 F. Supp. 2d at 268 ("Determining what motivated a particular person or entity is generally not an appropriate subject matter for expert testimony") (collecting cases).

Moreover, Opinion Three should be excluded under Rule 403, because any purported probative value is "substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Fed. R. Evid. 403. The Supreme Court and the Second Circuit have "noted the uniquely important role that Rule 403 has to play in a district court's scrutiny of expert testimony, given the unique weight such evidence may have in a jury's deliberations." *Nimely*, 414 F.3d at 397. "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses." *Id.* (quoting *Daubert*, 509 U.S. 595) (internal citation omitted).

Opinion Three is not relevant to any issue, and it has no probative value whatsoever. Hayes' opinion that Express Scripts is motivated by profit to ignore fraudulent or high-dollar claims is inconsistent with the facts, as Express Scripts promotes its Compound Management Program and it repeatedly advised NYCTA to restrict its compound drug coverage. *See supra* p. 18-19.

As such, Opinion Three should be excluded because "its minimal probative value is substantially outweighed by its prejudicial effect." *Bloomberg*, 2010 WL 3466370, at *18 (excluding expert opinion that would "serve merely to distract the jury's attention"); *Mirena*, 169 F. Supp. 3d at 421 (excluding expert opinion that is not relevant and "would waste time, and would unfairly prejudice Plaintiffs").

Dated: March 31, 2021

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 31st day of March, 2021, the foregoing was filed electronically with the Clerk of Court, to be served by operation of the Court's electronic filing system upon all counsel of record.

s/ Elizabeth A. Bozicevic